SEP 22 2000

Summary of Safety and Effectiveness

K002005
Page 1 of 2

1. Device Name

BolusPro Ultra option for CT scanners

2. Submitter

Marconi Medical Systems, Inc.,
595 Miner Road
Highland Heights
OH 44143
(440) 473-3000

3. Intended Use Of Device and its Main Features

The option is used for whole body computed tomography applications as an aid for planning and performing of bolus contrast-enhanced scans.

The intake of contrast material is tracked in real-time to provide precise matching of scan timing to the peak bolus phase for optimum contrast enhancement of the tissues of interest. One particular use is for optimizing enhancement of blood vessels for CT Angiography.

4. Predicate Devices

- CT-Twin *flash* submitted in "HRSW Option for CT-Twin Flash" K945512.
- HeliCAT CT scanner, K930090
- AngioCT option, K932508/B
- GE-YMS CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options, K970606, cleared on April 4, 1997.
- Toshiba America Medical Systems, Inc. – Asteion CT Scanner, TSX-021A, K982787, cleared on October 21, 1998. This scanner includes the SureStart application as per Toshiba's August 3rd, 1999 press release (included as Appendix J).
- Algotec Systems Ltd. – ProVision workstation, K980648 and K954678.

K002005
Page 2 of 2

5. Safety and Effectiveness

The safety of the option is assured by adherence to 21 CFR 820 Quality System Regulations and to International Standards. Potential hazards are identified in a hazard analysis and controlled in the following manner:

Software safety of the option is assured by the company procedures that conform to accepted practices. Quality assurance procedures were adhered to, and test results demonstrate that the option specifications and functional requirements were met.

Electrical and Mechanical safety is assured by adherence to IEC 601-1 standards.

Radiation safety is assured by compliance with 21 CFR, Subchapter J performance standards. In addition, the BolusPro Ultra Operation Manual contains instructions and warnings how to keep exposure to the minimum necessary.

6. Substantial Equivalency Statement

Based on the above considerations, it is Marconi's opinion that scanners incorporating the BolusPro Ultra option is substantially equivalent in safety and effectiveness to the predicate devices, CT Twin flash, K945512 and HeliCAT, K930090.

In our opinion the BolusPro Ultra option is also substantially equivalent to the SmartPrep option included in GE-YMS CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options as cleared in K970606.

We also claim substantial equivalence to the Toshiba America Medical Systems, Inc. Asteion CT Scanner, TSX-021A, K982787, cleared on October 21, 1998. This scanner includes the SureStart application as per Toshiba's August 3rd, 1999 press release (included as Appendix J)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2000

Robert L. Turocy
Regulatory Affairs & Compliance Manager
Marconi Medical Systems, Inc.
595 Miner Road
Highland Heights, OH 44143

Re: K002005
BolusPro Ultra Option
Dated: June 30, 2000
Received: July 3, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Turocy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(K) Number (if known): K002005

Device Name: BolusPro Ultra

Indications for Use:

The BolusPro Ultra is used for whole body computed tomography applications, specifically for optimizing the timing of contrast – enhanced scanning.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Per 21 CFR 801.109)

OR

Over-The Counter Use

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002005